



FREE TRANSMITTAL

Complete if known

Application Number: 09/980,217

Filing Date: May 6, 2002

First Named Inventor: Peter Leadlay et al.

Title: POLYKETIDES AND THEIR SYNTHESIS

TOT. AMT. OF PAYMENT: (1) + (2) + (3) = \$ 55.00

Our File No.: 0380-P02746US0

METHOD OF PAYMENT (check one)

1. The Commissioner is hereby authorized to:

- ☐ Charge indicated fees
☒ Charge additional fees
☒ Credit overpayments

to the account of DANN, DORFMAN, HERRELL AND SKILLMAN

Deposit Account Number 04-1406

2. Payment enclosed:

Check in the amount of \$ 55.00

FEE CALCULATION

1. FILING FEE

Fee Description	Fee Paid
Utility filing fee	
Design filing fee	
Plant filing fee	
Reissue filing fee	
Provisional filing fee	
SUBTOTAL (1)	\$ 0.00

2. CLAIMS

	Extra	Fee	Fee Paid
Total Claims Presented	20	0	9.00/18.00
(a)			
Independent Claims Presented	3	0	42.00/84.00
(b)			
Multiple Dependent Claim (first presentation)		0	
(a) Enter 20 or number previously paid for			
(b) Enter 3 or number previously paid for			
SUBTOTAL (2)			\$ 0.00

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Fee Description	Fee Paid
Surcharge-late filing fee or oath	
Surcharge - late provisional filing fee or cover sheet	
Non-English specification	
For filing a request for reexamination	
Requesting publication of SIR prior to Examiner action	
Requesting publication of SIR after Examiner action	
Extension for response within first month	55.00
Extension for response within second month	
Extension for response within third month	
Extension for response within fourth month	
Notice of Appeal	
Filing a brief in support of an appeal	
Request for oral hearing	
Petition to institute a public use proceeding	
Petition to revive unavoidably abandoned application	
Petition to revive unintentionally abandoned application	
Issue fee	
Advance Order (10 copies)	
Publication Fee	
Petitions to the Commissioner	
Petitions related to provisional applications	
Submission of Information Disclosure Stmt.	
Recording each patent assignment per property (times number of properties)	
Filing a submission after final rejection (37 CFR 1.129(a))	
For each additional invention to be examined (37 CFR 1.129(b))	
Other fee (specify)	
SUBTOTAL (3)	\$ 55.00

Submitted By:

Typed or

Printed Name Patrick J. Hagan Reg. Number 27,643

Signature Patrick J. Hagan

Date June 4, 2004

Deposit Account User ID
04-1406



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of) Examiner: Kathleen M. Kerr
Peter Leadlay et al.) Art Unit: 1652
Serial No. 09/980,217)
Filed: May 6, 2002)
For: "Polyketides and Their)
Synthesis")

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Our File No. 0380-P02746USO

Certificate of Mailing Under 37 C.F.R. §1.8(a):

I hereby certify that this correspondence is being deposited on June 4, 2004 with the United States Postal Service as first-class mail in an envelope properly addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Caren Burgoon
Caren Burgoon

Petition for Extension of Time Under 37 C.F.R. §1.136(a):

The undersigned hereby petitions for an extension of time of one (1) month beyond the time period set forth in the Restriction Requirement. A check in the amount of \$55.00 to cover this fee is enclosed. Please charge any deficiency or credit any overpayment to Deposit Account No. 04-1406.

06/09/2004 WASFAW1 00000063 09980217

01 FC:2251

55.00 OP

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TRAVERSAL OF RESTRICTION REQUIREMENT

A restriction requirement under 35 U.S.C. §§121 and 372 was set forth in the Official Action dated April 6, 2004 in the

above-identified patent application. It is the Examiner's position that claims 1-47 in the present application are drawn to ninety-one (91) patentably distinct inventions.

At the outset it is noted that a shortened statutory response period of one (1) month was set in the April 6, Official Action. The initial due date for response, therefore, was May 6, 2004. A petition for a one month extension of the response period is presented with this response, which is being filed within the one month extension period.

Applicants respectfully submit that the restriction requirement set forth above is improper for failure to comply with the relevant provisions of the Manual of Patent Examining Procedure (M.P.E.P.) pertaining to unity of invention determinations.

The present application was filed under 35 U.S.C. §371 as a U.S. national stage application under the Patent Cooperation Treaty. As stated in §1893.03(d) of the M.P.E.P.:

Examiners are reminded that unity of invention (not restriction) practice is applicable in international applications (both Chapter I and II) and in national stage (filed under 35 U.S.C. 371) applications...

The principles of unity of invention are used to determine the types of claimed subject matter and the combinations of claims to different categories of invention that are permitted to be included in a single international or national stage patent application. The basic principle is that an application should relate to only one invention or, if there is more than one invention, that applicant would have a right to include in a single application only those inventions which are so linked as to form a single general inventive concept.

A group of inventions is considered linked to form a single general inventive concept where there is a technical relationship among the inventions that involves at least one common or corresponding special technical feature. The expression special technical features is defined as meaning those technical features that define the contribution which each claimed invention, considered as a whole, makes over

the prior art.... Note also examples 1-17 of Annex B Part 2 of the PCT Administrative Instructions as amended 01 July 1992 contained in Appendix AI of the M.P.E.P.

It is noteworthy that, during the international stage of this application, claims 1-45 were determined, under the PCT unity of invention rules, to be drawn to only fourteen (14) patentably distinct inventions, as indicated in the International Search Report issued January 8, 2001. The fourteen patentably distinct inventions were as follows:

- Group 1: Claims 1-45 drawn, in part, to DNA comprising the complete monensin (mon) gene cluster or part thereof which encodes a polypeptide at least 80% identical to one of SEQ ID NOS: 12-33; vectors, hybridization probes, and cells comprising the DNA; uses of the monensin genes; DNA molecules, including vectors, encoding hybrid polyketide synthases containing at least one monensin domain and cells containing the DNA molecule; methods of producing polyketides containing monensin domains; methods of producing *S. cinnamonensis* capable producing enhanced levels of monensin; and methods for expressing a heterologous gene in *S. cinnamonensis*;
- Group 2: Claims 1, 8-12, and 14 drawn to DNA molecules, vectors, transformed cells, and hybridization probes comprising a sequence encoding a polypeptide at least 80% identical to SEQ ID NO: 5 (GdhA) and their uses;
- Group 3: Claims 1, 8-12, and 14 drawn to DNA molecules, vectors, transformed cells, and hybridization probes comprising a sequence encoding a polypeptide at least 80% identical to SEQ ID NO: 6 (DapA) and their uses;
- Group 4: Claims 1, 8-12, and 14 drawn to DNA molecules, vectors, transformed cells, and hybridization probes comprising a sequence encoding a polypeptide at least 80% identical to SEQ ID NO: 7 (Orf3) and their uses;
- Group 5: Claims 1, 8-12, and 14 drawn to DNA molecules, vectors, transformed cells, and hybridization

probes comprising a sequence encoding a polypeptide at least 80% identical to SEQ ID NO: 8 (Orf4) and their uses;

- Group 6: Claims 1, 8-12, and 14 drawn to DNA molecules, vectors, transformed cells, and hybridization probes comprising a sequence encoding a polypeptide at least 80% identical to SEQ ID NO: 9 (Orf5) and their uses;
- Group 7: Claims 1, 8-12, and 14 drawn to DNA molecules, vectors, transformed cells, and hybridization probes comprising a sequence encoding a polypeptide at least 80% identical to SEQ ID NO: 10 (Orf6) and their uses;
- Group 8: Claims 1, 8-12, and 14 drawn to DNA molecules, vectors, transformed cells, and hybridization probes comprising a sequence encoding a polypeptide at least 80% identical to SEQ ID NO: 11 (Orf7) and their uses;
- Group 9: Claims 1, 8-12, and 14 drawn to DNA molecules, vectors, transformed cells, and hybridization probes comprising a sequence encoding a polypeptide at least 80% identical to SEQ ID NO: 34 (Orf29) and their uses;
- Group 10: Claims 1, 8-12, and 14 drawn to DNA molecules, vectors, transformed cells, and hybridization probes comprising a sequence encoding a polypeptide at least 80% identical to SEQ ID NO: 35 (LipB) and their uses;
- Group 11: Claims 1, 8-12, and 14 drawn to DNA molecules, vectors, transformed cells, and hybridization probes comprising a sequence encoding a polypeptide at least 80% identical to SEQ ID NO: 36 (Orf31) and their uses;
- Group 12: Claims 1, 8-12, and 14 drawn to DNA molecules, vectors, transformed cells, and hybridization probes comprising a sequence encoding a polypeptide at least 80% identical to SEQ ID NO: 37 (Orf32) and their uses;
- Group 13: Claims 1, 8-12, and 14 drawn to DNA molecules, vectors, transformed cells, and hybridization probes comprising a sequence encoding a polypeptide at least 80% identical to SEQ ID NO: 38 (AmtA) and their uses; and

Group 14: Claims 43 and 44 drawn to a method for
 expressing a heterologous *S. cinnamomensis*
 under the control of actII/orf4.

Plainly, the restriction requirement in the present case fails to comply with the established United States Patent and Trademark Office practice of following the international rules regarding unity of invention in the prosecution of applications filed under §371.

In light of all the foregoing, Applicants respectfully request that the restriction requirement set forth in the April 6, 2004 Official Action be withdrawn and replaced with the restriction requirement set forth in the International Search Report dated January 8, 2001, with newly added claims 46 and 47 being included with Group 1.

At the very least, Applicants request that Groups 10-15, 20, and 21 of the April 6, 2004 restriction requirement be examined together on the merits. The identified groups relate to DNA encoding MonAI through MonAVIII. Importantly, the MonAI through MonAVIII genes encode proteins with related functions, i.e. they are polyketide synthase (PKS) multienzymes, and the genes are required for the biosynthesis of monensin (see, for example, page 19, lines 1-7; page 22, lines 2-8; and Figure 3). Accordingly, Applicants submit that Groups 10-15, 20, and 21 relate to a single inventive concept possessing a common special technical feature, i.e. encoding a PKS multienzyme required for the biosynthesis of monensin.

In order to be fully responsive to the present restriction requirement, Applicants hereby elect, with traverse, the subject matter of Group 13 for consideration in this application, namely claims 1-3, 6-12, 30-34, 37, 38, 46, and 47. These claims are drawn to a DNA encoding MonAIV and related products.

Applicant's election of Group 13 is without prejudice to their right to file one or more divisional applications as provided in 35 U.S.C. §121 on the subject matter of all claims ultimately withdrawn from consideration in the present

application.

Early and favorable action on the merits of this application
is earnestly solicited.

Respectfully submitted,

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